



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: June 15, 2020

SUBJECT: Efficacy Review for White,
EPA Reg. No. 777-128
DP Barcode: 457962
E-submission No. 50912

FROM: Nicole Karikari
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Nicole Karikari

THRU: Cesar E. Cordero
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: July 29, 2020

Cesar E. Cordero

TO: Jacqueline Hardy, PM 34/ Emilia Oiguenblik
Regulatory Management Branch II
Antimicrobials Division (7510P)

APPLICANT: Reckitt Benckiser, LLC
One Phillips Parkway
Montvale, NJ 07645

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (40% C ₁₂ , 50% C ₁₄ , 10% C ₁₆) dimethyl benzyl ammonium chloride	0.960%
Octyl decyl dimethyl ammonium chloride	0.720%
Dioctyl dimethyl ammonium chloride	0.288%
Didecyl dimethyl ammonium chloride	0.432%
<u>Other Ingredients</u>	97.600%
<u>Total</u>	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Concentrated Liquid (Dilutable)

Submission type: Label Amendment

Currently registered efficacy claim(s): Concentrated liquid laundry pre-soak disinfectant treatment (bactericidal and virucidal) and non-food contact laundry sanitizer.

Requested action(s): Add virucidal disinfection claims for use against SARS-CoV-2

Documents considered in this review:

- Cover letter from applicant to EPA dated 5/28/2020
- Proposed label dated 5/28/2020
- Data Matrix (EPA Form 8570-35) dated 5/28/2020
- One efficacy study
 - MRID 51158102 dated 5/28/2020
 - Supplemental information dated 6/8/2020
- Confidential Statement of Formula (EPA Form 8670-4)
 - Basic formulation dated 1/10/2018
 - Alternate Formulation 2 dated 1/10/2018
 - Efficacy testing was conducted on formula # e0042-196 of approved CSF Alternate #2 (Crisp Linen).
- Through an AD Efficacy Mailbox communication dated 6/29/2020, the agency indicated to a registrant that it was acceptable to use ASTM E1053 to support virucidal test for pre-soak disinfection claims,

II PROPOSED DIRECTIONS FOR USE

“DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

(Read the entire label before using the product.)

[or ††]Presoak (to Disinfect)(Disinfection)(Disinfectant) (Directions):** Pour (two)(2) (caps) (capfuls) (150 mL) (each) (filled to (level) (line) (X)) into (1 gallon)(4 liters) (of) cold (86°F/20°C) water. Soak items for 15 minutes. Rinse thoroughly with clean water or machine wash as directed.

[Place Holder for Dosing Cap Graphics]

(For Odor Removal (Directions)) (To Remove Odors) (To Deodorize)

Add (X) (fl oz) (mL) (cap(s)) (capful(s)) (each) (filled to (level) (line) (X)) of the dosing (cup)(cap)) to the fabric softener (compartment) (drawer) of the washing machine or directly to your rinse cycle wash

(For Laundry Sanitizer) (For Laundry Sanitization) (Directions))

(For) Single Dose (use) (for) (all washing machine (types)(styles)):

Add (full) contents of (pack)(package)(sachet) to your fabric softener (drawer)(compartment) or directly to the rinse cycle.

For (Standard)(Top Load) (Non-HE) (Non High Efficiency) Machine(s):

Add (150 mL) ((X) (cap(s)) (capful(s))) (each) filled to (level)(line) (X) of the dosing (cup)(cap)) to the fabric softener (compartment)(drawer) (of the washing machine) or directly to your rinse cycle wash.

[Place Holder for Dosing Cap Graphics]

For (High Efficiency)(HE)(Front Load) Machine(s):

Add (100 mL) ((X) (cap(s)) (capful(s))) (each) filled to (level)(line)(X) of the dosing (cup)(cap)) to the fabric softener (compartment)(drawer) (of the washing machine) or directly to your rinse cycle wash. (If total amount does not fit, add the remaining amount into the (compartment)(drawer) when rinse cycle wash begins.)

[Place Holder for Dosing Cap Graphics]

To Sanitize: add to rinse cycle and leave product in (contact)(rinse cycle) for 16 minutes."

III STUDY SUMMARIES

1.	MRID	51158102
Study Objective		Disinfectant - Virucidal
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 121-283
Experimental Start Date		4/23/2020
Study Completion Date:		5/28/2020
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Severe Acute Respiratory Syndrome-Related Coronavirus 2(SARS-CoV-2) (COVID-19 Virus) Strain: USA-WA1/2020 Source: BEI Resources, NR-52281
Indicator Cell Culture		Vero E6 cells Source: ATCC CRL-1586
Test Method		ASTM International E1053-20 "Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces"; Protocol Number: 121.10.03.23.20
Application Method		Liquid
Test Substance Preparation	Name/ID	Lysol Laundry Sanitizer, EPA Reg. No. 777-128, Formula #e0042-196
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	2250-085 2250-095 2250-096
	Preparation	Tested concentration: LCL Tested Dilution: 1:28 (1 part test substance + 27 parts diluent) Diluent: 402 ppm AOAC Hard Water
Soil load		5% Fetal bovine serum in viral inoculum
Carrier type, # per lot		Sterile glass carrier, 1 per lot
Test conditions		Contact time: 4 minutes 45 seconds Temperature: 21°C Relative humidity: 34%
Neutralizer		MEM + 10% Fetal Bovine Serum (FBS) + 0.5% Polysorbate 80 +0.5% Lecithin
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Protocol Amendment: The origin of the challenge virus: strain USA-WA1/2020 was isolated from an oropharyngeal swab from a patient with a respiratory illness who had recently returned from travel to the affected region of China and developed clinical disease (COVID-19) in January 2020 in Washington, USA (https://www.beiresources.org/Catalog/animalviruses/NR-52281.aspx).

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log ₁₀ TCID ₅₀ /carrier)	
			Lot 2250-085	Lot 2250-095	Lot 2250-095	(Log ₁₀ TCID ₅₀ /ml)**	(Log ₁₀ TCID ₅₀ /carrier)***
4 minutes 45 seconds, 1:128 dilution in 402 ppm AOAC Hard Water, 5% soil load							
51158102	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) Strain: USA-WA1/ 2020 Source: BEI Resources, NR-52281	10 ⁻¹ dilution	Cytotoxicity	Cytotoxicity	Cytotoxicity	5.50	5.10
		10 ⁻² to 10 ⁻⁷ dilution	Complete inactivation	Complete inactivation	Complete inactivation		
		Log ₁₀ TCID ₅₀ /ml**	≤ 2.50	≤ 2.50	≤ 2.50		
		Log ₁₀ TCID ₅₀ /carrier***	≤ 2.10	≤ 2.10	≤ 2.10		
		Log Reduction	≥ 3.00	≥ 3.00	≥ 3.00		

**Per carrier (0.40 mL of Undilute [100])

***Per assayed volume and per carrier

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51158102	Laundry pre-soak disinfectant, virucidal	Hard non-porous surface (glass carrier)	2.0 mL of test substance was added to the dried virus.; 1:28 (1 part test substance + 27 parts diluent	4 minutes 45 seconds	5%	402 ppm AOAC Hard Water	<ul style="list-style-type: none"> Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) Strain: USA-WA1/2020 	Yes

VI LABEL COMMENTS

Label Date/Identification Number: May 28,2020

1. The proposed label claims that the product, White, EPA Reg. No. 777-128, as a laundry presoak disinfectant against the following virus using the following dilution rate by total immersion application in the presence of 5% organic soil for a 15-minute contact time.

150 mL of product/1 gallon of water of up to 400 ppm hard water:

Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2)
(COVID-19 Virus) Strain: USA-WA1/2020

These claims are acceptable as they are supported by the submitted data. To clarify use directions for the end user, only one measurement system, either metric or imperial units, should be used throughout the label.

2. Make the following changes to the proposed label:

- a. On page 4,

- i. remove “(Hard) (tough) on bacteria...” as this statement is misleading and implies heightened efficacy.
- ii. remove “(even below 30°C) (so you can be confident) (that your laundry is sanitized and hygienically clean) (with every wash) (every time) (whatever temperature you wash at)” as these claims are misleading since the submitted efficacy data was conducted at room temperature (21°C) and the current language could imply effectiveness at temperatures below that of the submitted data.

- iii. “Germy” should be removed.

- b. On page 6, remove “(Even) For use in (any) (cold) (warm) (and / &) (hot) water (temperature(s))” as these claims are misleading.

- c. On page 7, remove “Works (effectively)(even) (at)(in) (low temperatures)(cold water)” as this claim is misleading.

- d. On page 8, remove “Kills 99.9% of bacteria*** that could cause skin infections such as {insert organisms from Appendix 1}” and “Kills 99.9% (Staphylococcus aureus) (and / &) (Klebsiella pneumoniae)*** that could cause skin infections”. These claims are not acceptable. The organism-illness link is not a direct correlation; it represents one possible, unlikely outcome from exposure to these organisms.

- e. On page 9,

- i. remove “Sanitizes (laundry) (clothing) (even) in cold (water) (washes)(!)” as this claim is misleading.

- ii. remove “Dial down to cold, (still) kills (99.9%) of (bacteria**) (viruses††) (and / &) (germs**)” as this claim is misleading.
 - iii. remove “cold” from “Kills 99.9% of (germs**) ((cold (and / &) flu) (viruses††)) (in pre-soak)” as this claim is misleading. To qualify for “cold virus” claims, registered products should have acceptable efficacy data for either one small non-enveloped virus or two enveloped and/or large non-enveloped viruses from the following list: Rhinoviruses (small non-enveloped), Adenoviruses (large non-enveloped), Respiratory Syncytial virus (enveloped), Coronaviruses (enveloped), Human Parainfluenza viruses (enveloped).
- f. On page 10, under the “USE DIRECTIONS” for “Presoak”, specify **complete immersion for product application is needed**.